

**IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TEXAS
TYLER DIVISION**

CAMI JO TICE-HAROUFF, on behalf of
herself and her patients,

Plaintiff,

v.

CAROLE JOHNSON in her official capacity
as Administrator of the Health Resources and
Services Administration of the United States
Department of Health and Human Services;
**HEALTH RESOURCES AND SERVICES
ADMINISTRATION OF THE UNITED
STATES DEPARTMENT OF HEALTH
AND HUMAN SERVICES; XAVIER
BECERRA**, in his official capacity as
Secretary of the United States Department of
Health and Human Services; and **UNITED
STATES DEPARTMENT OF HEALTH
AND HUMAN SERVICES**,

Defendants.

No. _____

VERIFIED COMPLAINT

Jury Trial Demanded

PLAINTIFF'S VERIFIED COMPLAINT

Plaintiff, Dr. Cami Jo Tice-Harouff, DNP, APRN, FNP-C, on behalf of herself
and her patients, for her verified complaint against Defendants, states:

INTRODUCTION

1. This case is a challenge under the Administrative Procedure Act to the federal government's final decision to change a health insurance coverage mandate under the Affordable Care Act (ACA) without using the notice-and-comment rulemaking process to issue the change.

2. The ACA requires most health plans to provide coverage, without cost sharing, of women's preventive services as set forth in guidelines by Defendant Health Resources and Services Administration (HRSA), *see* 42 U.S.C. § 300gg-13(a)(4). Since 2016 that requirement has included coverage of instruction in fertility

awareness-based methods of family planning. But in December 2021, the government issued a decision to delete the language requiring coverage of that service.

3. This final agency action harms women and their healthcare professionals who depend on these insurance benefits. Plaintiff Dr. Cami Jo Tice-Harouff, a Family Nurse Practitioner in Longview, Texas, regularly instructs patients in fertility awareness-based methods of family planning both locally and by telehealth, and she bills her patients' health insurance plans for those services.

4. The government should have considered many important issues before deleting coverage of these services, including their importance to women and to their health professionals. But the government not only failed to consider those issues—it made this change without using the notice-and-comment process at all, despite the Administrative Procedure Act's mandate that notice-and-comment rulemaking be used before changing a requirement that binds external parties. Women should not have to fear losing their doctor and their medical treatment as a result of backroom government decisions.

5. Dr. Tice-Harouff thus challenges the government's action on two grounds under the Administrative Procedure Act. *First*, the government unlawfully failed to follow notice-and-comment rulemaking procedures. *Second*, the government's action was arbitrary and capricious, and not the product of reasoned decision-making.

6. A temporary restraining order, and preliminary and permanent injunctive relief, are necessary to prevent women and health professionals from being harmed by this change, which goes into effect for health plan years starting after December 30, 2022. Health plan issuers in Texas and around the country are already in the process of obtaining approval of plans set to take effect in January 2023.

JURISDICTION & VENUE

7. This Court has subject-matter jurisdiction under 28 U.S.C. § 1331 because this action arises under the U.S. Constitution and federal law.

8. This Court also has jurisdiction under 28 U.S.C. § 1346(a) because this is a civil action against the United States.

9. Additionally, this Court has jurisdiction under 28 U.S.C. § 1361 to compel an officer of the United States or any federal agency to perform his or her duty.

10. This Court has jurisdiction to review Defendants' unlawful actions and enter appropriate relief under the Administrative Procedure Act, 5 U.S.C. §§ 553, 701–06.

11. This court has jurisdiction to issue equitable relief to enjoin ultra vires agency action. *Larson v. Domestic & Foreign Com. Corp.*, 337 U.S. 682, 689–91 (1949).

12. This case seeks declaratory and other appropriate relief under the Declaratory Judgment Act, 28 U.S.C. §§ 2201–2202, 5 U.S.C. § 705–06, Federal Rule of Civil Procedure 57, and the Court's inherent equitable powers.

13. This Court may award costs and attorneys' fees under the Equal Access to Justice Act, 28 U.S.C. § 2412.

14. Venue is proper in this Court under 28 U.S.C. § 1391 because a substantial part of the events or omissions giving rise to the claims occurred in this district, and a substantial part of property that is the subject of the action is situated here, because this district and this division is where Plaintiff is situated and is regulated by Defendants' actions. Defendants are United States agencies or officers sued in their official capacities. A substantial part of the events or omissions giving rise to the Complaint occurred within the Eastern District of Texas.

PARTIES

15. Plaintiff Cami Jo Tice-Harouff, DNP, APRN, FNP-C, is a family nurse practitioner whose home and office are each located in Longview, Texas, and Gregg County, Texas. She sues on her own behalf and on behalf of her current and future patients.

16. Defendant Carole Johnson is Administrator of the Health Resources and Services Administration of the United States Department of Health and Human Services. She is responsible for the overall operations of HRSA, including HRSA's implementation of the women's preventive services mandate at 42 U.S.C. § 300gg-13(a)(4). Defendant Johnson is sued in her official capacity. Her address at HRSA is 5600 Fishers Lane Rockville, MD 20857.

17. Defendant Health Resources and Services Administration (HRSA) is a federal agency within the executive branch of the U.S. government, including under 5 U.S.C. § 551 and 701(b)(1). HRSA is an operating division of the United States Department of Health and Human Services. Its address is 5600 Fishers Lane Rockville, MD 20857

18. Defendant Xavier Becerra is the Secretary of the U.S. Department of Health and Human Services (HHS), and is sued in his official capacity. He is responsible for the overall operations of the Department, including of the Health Resources and Services Administration. His address at HHS is 200 Independence Ave SW, Washington, DC 20201.

19. Defendant U.S. Department of Health and Human Services (HHS) is a federal agency within the executive branch of the U.S. government, including under 5 U.S.C. § 551 and 701(b)(1). Its address is 200 Independence Ave SW, Washington, DC 20201.

20. Collectively and as applicable, all defendants are referred to herein as "the government."

FACTUAL ALLEGATIONS

I. The government removed fertility awareness-based methods of family planning from its contraceptive mandate.

21. Under the Affordable Care Act (ACA):

A group health plan and a health insurance issuer offering group or individual health insurance coverage shall, at a minimum provide coverage for and shall not impose any cost sharing requirements for . . .

. . .

(4) with respect to women, such additional preventive care and screenings . . . as provided for in comprehensive guidelines supported by the Health Resources and Services Administration for purposes of this paragraph.

42 U.S.C. § 300gg-13(a)(4) (also referred to as section 2713 of the Public Health Service Act).

22. Although the statute refers to these as “guidelines,” they are mandatory by virtue of the prefatory language of 42 U.S.C. § 300gg-13(a), which says plans and issuers “shall” provide coverage and “shall not” impose cost sharing for the items listed in the guidelines.

23. Using that authority, Defendants HRSA and its Administrator, and upon information and belief Defendants HHS and its Secretary by virtue of their authority over HRSA, have issued guidelines describing which women’s preventive services must be covered without cost sharing under § 300gg-13(a)(4).

24. According to HRSA, since guidelines published at least as far back as 2016, the women’s preventive care and screenings coverage requirements under § 300gg-13(a)(4) have required group health plans and health insurance issuers to offer coverage without cost-sharing of “instruction in fertility awareness-based methods”

of family planning. HRSA's website lists the coverages that were set forth in its "2016 Guidelines."¹

25. But in December 2021, the government changed these guidelines to delete the sentence requiring coverage without cost sharing of "instruction in fertility awareness-based methods" of family planning. See Exhibit A at 2–3, under "Contraception," comparing "Current Guidelines" to "Updated Guidelines Beginning With Plan Years Starting in 2023."²

26. This agency action at Exhibit A is hereinafter referred to as the "2021 Guidelines," and its deletion of this language is the subject of this lawsuit.

27. Under the 2021 Guidelines, applicable health plans and coverages "are required to provide coverage without cost sharing consistent with these guidelines beginning with the first plan year (in the individual market policy year) that begins on or after December 30, 2022." 2021 Guidelines at note *.

28. The one-year timeframe for the 2021 Guidelines effective date is mandated by § 300gg-13(b)(2).

29. Thus the government issued the 2021 Guidelines as a final matter in December 2021, with an effective date on plans that start after December 30, 2022.

30. HRSA refers to its issuance of the 2021 Guidelines as "the formal action by the Administrator under Section 2713." Ex. A at 7–8.

31. HRSA also calls its issuance of the 2021 Guidelines "the decision to update the Guidelines." Update to the Women's Preventive Services Guidelines, Update to the Women's Preventive Services Guidelines, 87 Fed. Reg. 1,763 (Jan. 12, 2022).

¹ HRSA, *Women's Preventive Services Guidelines* (2016), <https://bit.ly/3NBpi3x> (last visited May 24, 2022).

² Also available at HRSA, *Women's Preventive Services Guidelines* (2021), <https://bit.ly/3GcDLkc> (last visited May 24, 2022). HRSA subsequently published this change in the Federal Register at Update to the Women's Preventive Services Guidelines, 87 Fed. Reg. at 1,763 (noting the December date of the change).

32. The 2021 Guidelines are HRSA's final, post-deliberative decision about what coverages are required under § 300gg-13(a)(4).

33. Issuance of the 2021 Guidelines is a final agency action.

34. Under the guidelines that existed previous to the 2021 Guidelines, applicable health plans and issuers were required to cover "instruction in fertility awareness-based methods" of family planning with no cost sharing.

35. The effect of the December 2021 Guidelines' deletion of language that had required coverage of "instruction in fertility awareness-based methods" is that applicable health plans and issuers will no longer be required to cover those services under the guidelines authorized by § 300gg-13(a)(4).

II. Dr. Tice-Harouff bills insurance for fertility awareness-based methods of family planning.

36. Plaintiff Dr. Cami Jo Tice-Harouff, DNP, APRN, FNP-C, is a health professional who provides patients with instruction in fertility awareness-based methods of family planning.

37. Dr. Tice-Harouff bills patients' health insurance plans for providing this instruction.

38. Dr. Tice-Harouff has a Doctor of Nursing Practice degree in Advanced Practice Nursing from Samford University, a Master of Science in Nursing from Bellarmine University, and an undergraduate degree in Theology and Psychology from The Baptist College of Florida.

39. Dr. Tice-Harouff is a member of the American Association of Nurse Practitioners, Texas Nurse Practitioners, the East Texas Nurse Practitioner Association, the National League for Nursing, the Catholic Medical Association, Fertility Appreciation Collaborative to Teach the Science (FACTS), BOMA-USA (Billings Ovulation Method), and the National Association of Catholic Nurses.

40. Dr. Tice-Harouff has often taught academic courses to nursing students through various universities.

41. Dr. Tice-Harouff has worked in many community settings, including in nonprofit health programs for vulnerable populations and as a Registered Nurse, Sexual Assault Nurse Examiner.

42. Dr. Tice-Harouff currently practices as a family nurse practitioner.

43. Since March 2021, Dr. Tice-Harouff has served as the executive director of Hesed Health Clinic, a 501(c)(3) nonprofit charitable health clinic in Longview, Texas.

44. Dr. Tice-Harouff sees patients in person and by telehealth.

45. Dr. Tice-Harouff is licensed to practice in Texas. She is also licensed to provide telehealth on a full basis to patients in Delaware, Connecticut, Florida, and Nevada, and on a limited basis to patients in Kentucky and California. She is seeking to expand her licensure for telehealth to other states soon, such as Rhode Island, to address the shortage of healthcare providers.

46. As part of her practice, Dr. Tice-Harouff provides general women's health, which includes medical management of women's reproductive health needs, and instruction in fertility awareness-based methods of family planning.

47. Dr. Tice-Harouff offers instruction and medical support in several fertility awareness-based methods of family planning, including NaProTechnology care, Creighton Model FertilityCare education, and the Marquette Method of family planning. She also plans to add FEMM Medical Management to her services.

48. These fertility awareness-based methods of family planning help patients avoid or achieve pregnancy in many situations, including while breastfeeding.

49. Dr. Tice-Harouff's instruction of patients in these fertility awareness-based methods of family planning has been covered by the HRSA guidelines issued under § 300gg-13(a)(4) for several years, but will no longer be covered when the 2021 Guidelines go into effect.

50. Many women have medical, philosophical, or religious reasons for choosing fertility awareness-based methods of family planning. Birth control, for instance, sometimes creates harmful side effects, like blood clots, weight gain, or increased anxiety and depression in some women. That makes fertility awareness-based methods of family planning some women's only option without serious endangerment to their health. Fertility awareness-based methods of family planning are also the method many women chose based on their philosophical, moral, or religious beliefs.

51. Dr. Tice-Harouff's fertility-affirming family planning thus allows patients to live according to healthy living practices and their core principles while seeking to choose the best care for their families

52. Dr. Tice-Harouff's appointments providing instruction in fertility awareness-based methods of family planning are minimally one hour long and often last ninety to one hundred twenty minutes.

53. Dr. Tice-Harouff sees such patients about six times in the first five months that she begins providing them instruction in fertility awareness-based methods of family planning.

54. Dr. Tice-Harouff bills and receives payment from many of her patients' insurance plans for her instruction in fertility awareness-based methods of family planning.

55. For patients who have insurance coverage, Dr. Tice-Harouff's instructional sessions are reimbursed by about \$300 to \$450 per encounter from insurance coverage for her provision of instruction in fertility awareness-based methods of family planning.

56. In the last six months, Dr. Tice-Harouff's instruction in fertility awareness-based methods of family planning have generated at least \$20,000 thousand dollars in health insurance reimbursement payments.

57. As a service to the needy, Dr. Tice-Harouff volunteers for Hesed Health Clinic, and she arranges for her health care reimbursement payments to go to Hesed Health Clinic in order to benefit that nonprofit organization and the people for whom the clinic provides care.

58. Standardized coding exists to bill insurance companies for instruction in fertility awareness-based methods of family planning (also referred to as “natural family planning”), as an item that has heretofore been covered by the HRSA Guidelines.³

59. Dr. Tice-Harouff receives referrals to provide care to patients around the country, and she cares for patients in various states where she is licensed or is authorized to work with a medical doctor in that state.

60. Dr. Tice-Harouff is an in-network provider for many large, well-known, and commonly carried group health plans and health insurance issuers.

61. The state where a patient’s plan was issued is often not the only state in which the patient may receive care. For example, many plans provided by employers are issued in one state but cover employees of that company who live in many other states, and those plans give patients in-network and out-of-network options for care in those states, including for no-cost-sharing preventive care, or through telehealth.

62. Dr. Tice-Harouff accepts health insurance issued in any state. She provides care and bills insurance for a patient so long as she is licensed to provide care to the patient based on the patient’s physical location during treatment, is recognized as a provider by their plan or issuer, and other applicable conditions are met.

³ American College of Obstetricians and Gynecologists, *Women’s Preventive Services Initiative (WPSI), 2021 Coding Guide* at 4, 26 (2021), <https://bit.ly/3z0axmX> (last visited May 24, 2022) (listing “Coding for Natural Family Planning” as “Z30.02 Counseling and instruction in natural family planning to avoid pregnancy.”)

63. Some of Dr. Tice-Harouff's patients change or may change insurance plans during a year or annually, either due to life changes, open enrollment opportunities, or for other reasons, such as premium increases.

64. Uniform mandatory coverage of instruction in fertility awareness-based methods of family planning without cost sharing allows patients to continue to receive uninterrupted care despite different changes that can occur to their health insurance coverage.

65. Issuers revise benefits each year, and state health regulators approve coverage for health insurance plans each year.

66. Group health plans and health insurance issuers are already in the process of applying for approval for their plan years that would begin on January 1, 2023.⁴

III. Dr. Tice-Harouff and her patients will be harmed by the government's removal of fertility awareness-based methods from the women's preventive services guidelines.

67. Without insurance coverage and without cost-sharing for fertility-awareness-based methods of family planning, Dr. Tice-Harouff and her patients will suffer both financially and in their health outcomes.

68. Upon information and belief, without the explicit requirement in HRSA's women's preventive services guidelines for several years, many health insurance plans would not have covered instruction in fertility awareness-based methods of family planning, either at all or without cost-sharing.

69. Upon information and belief, many health insurance plans will not cover instruction in fertility awareness-based methods of family planning at all, or will cover it but impose cost-sharing, in coverage subject to the 2021 Guidelines.

⁴ See, e.g., Texas Department of Insurance, *Life/Fraternal, Accident and Health Insurers and Group Hospital Service Corporations, 2021/2022 Filing Smart*, <https://bit.ly/3Gdxch8> (last visited May 24, 2022) (setting forth multiple deadlines beginning in March 2022 for health insurers to file documents for their next plan year).

70. Insurance coverage, and coverage without cost-sharing, is key to access to care. In the past, HHS has acknowledged that research shows that “cost sharing can be a significant barrier” to obtaining family planning services. Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act, 77 Fed. Reg. 8,725, 8,728 (Feb. 15, 2012) (to be codified at 26 C.F.R. 54).

71. HHS has concluded that including services in the women’s preventive care guidelines—specifically in the “contraception” category where HRSA previously included language on fertility awareness-based methods—has increased coverage of those services for tens of millions of women, has decreased their costs, and has increased their use of those services, especially concerning services that would cost hundreds of dollars, such as for patients in high deductible health plans.⁵

72. In Dr. Tice-Harouff’s experience, patients are less likely to pursue medical care, and instruction in fertility awareness-based methods of family planning in particular, if that care is not covered or is not covered without cost-sharing.

73. For example, Dr. Tice-Harouff has patients whose coverage of fertility awareness-based methods of family planning would be subject to a high deductible, and her care would cost them hundreds of dollars each month, if this service was not covered without cost-sharing as mandated by the Guidelines. Dr. Tice-Harouff also has other patients who face financial difficulties and would struggle to pay for instruction in fertility awareness-based methods of family planning without coverage or if cost-sharing is imposed.

74. If health insurance plans choose not to cover instruction in fertility awareness-based methods of family planning, either at all or without cost-sharing,

⁵ Assistant Secretary for Planning and Evaluation, *Access to Preventive Services without Cost-Sharing: Evidence from the Affordable Care Act*, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES at 1, 9–10 (Jan. 11, 2022), <https://bit.ly/3lEHWM5>.

Dr. Tice-Harouff's current and future patients would be unable or less able to pay for her instruction, and would suffer negative health outcomes as a result.

75. Dr. Tice-Harouff will face reduced demand for and compensation for her instruction in fertility awareness-based methods of family planning under the 2021 Guidelines.

76. She will likely lose existing patients, have fewer new patients, have fewer patient follow-up sessions, have more patients self-pay at discounted rates below insurance reimbursements, and have more patients participate in charity care, under the 2021 Guidelines.

77. Fewer of Dr. Tice-Harouff's current and future patients will likely know that they have the option of fertility awareness-based methods of family planning from her, fewer patients will avail themselves of it, and fewer patients will be able to afford it, under the 2021 Guidelines.

78. Women who practice fertility awareness-based methods make serious personal and financial decisions in seeking to choose the best care for their families consistent with their philosophical or religious views. Removing mandatory insurance coverage of these services under the 2021 Guidelines will impose serious harm to these families.

79. Some patients who decline to use other methods of family planning for health, philosophical, or religious reasons will have access to no acceptable methods of family planning under the 2021 Guidelines.

80. Under the 2021 Guidelines' changes to fertility awareness-based methods instruction coverage, fewer patients will be able to maximize their individual health goals as under previous guidelines.

81. Dr. Tice-Harouff and her patients will likely experience reduced societal support for fertility awareness-based methods of family planning under the 2021 Guidelines.

82. HHS is imposing its own preferred method of family planning on all women by deleting language requiring coverage of instruction in fertility awareness-based methods from the 2021 Guidelines.

83. Dr. Tice-Harouff and her current and future patients are in danger of serious financial loss because of the 2021 Guidelines.

84. Because the government required insurers to cover instruction in fertility awareness-based methods of family planning under the previous Guidelines (which govern current coverage until plan years beginning after December 30, 2022), Dr. Tice-Harouff and her patients have a current, direct, and legally protected interest in the Guidelines' mandate of coverage of instruction in fertility awareness-based methods of family planning.

85. The 2021 Guidelines violate the APA rights of Dr. Tice-Harouff and her current and future patients.

86. The 2021 Guidelines cause legal wrongs to Dr. Tice-Harouff and her current and future patients.

87. Dr. Tice-Harouff and her current and future patients are adversely affected and aggrieved by the 2021 Guidelines.

88. The agency's lack of clarity and transparency in its process created confusion and disruption for Dr. Tice-Harouff, her patients, insurance plans, and the public.

89. Had the agency undergone a notice and comment process under the Administrative Procedure Act, Dr. Tice-Harouff and the public would have had proper notice of the change and the opportunity to submit public comments, which the agency would have had to consider and rationally discuss if it wished to finalize the change properly.

90. But the agency did not undergo the notice and comment process under the Administrative Procedure Act, and so Dr. Tice-Harouff and the public lost that

opportunity. She and others had no chance to urge the agency to keep its current mandate.

91. If the agency undergoes a future notice and comment process under the Administrative Procedure Act, Dr. Tice-Harouff intends to submit comments (1) raising reasons not to cut fertility awareness-based methods, (2) discussing her reliance interests in continued coverage for her services, and (3) suggesting possible alternatives to cutting instruction in fertility awareness-based methods.

92. There is a reasonable chance that the agency would make a different decision if the change challenged here is delayed, enjoined, and remanded unless and until the agency complies with the APA.

IV. The government’s removal of fertility awareness-based methods from the contraceptive mandate is a final agency action and a binding rule.

93. HRSA’s action to issue the 2021 Guidelines mandates or withdraws mandates of what insurance companies must or must not cover, and is a final agency action reviewable under the Administrative Procedure Act.

94. The 2021 Guidelines are an improperly issued rule.

95. HRSA’s announcement of the 2021 Guidelines as “supported” by the agency consummated the agency decision process and issued them in final form.

96. HRSA’s guidelines delineate the scope of obligations, rights, and benefits for the public, including for employers, insurers, providers, consumers, and insured women for the years specified, because HRSA intends its announcement of each set of guidelines to impose a mandate on insurance providers to cover the listed contraceptive services without cost-sharing.

97. HRSA insists on the binding nature of its Guidelines: “According to Section 2713 of the Public Health Service Act [42 U.S.C. § 300gg-13], private health insurers *must provide coverage* without cost sharing for the screenings and services in the guidelines. These guidelines *make sure* children and women receive a comprehensive

set of preventive services without having to pay a co-payment, co-insurance, or deductible.”⁶ (emphasis added).

98. HRSA’s guidelines are not labeled as optional or advisory, either for the agency’s officials or for the public.

99. In both its previous guidelines, which included coverage of “instruction in fertility awareness-based methods” of family planning, and its 2021 Guidelines which do not, HRSA insists that applicable health coverage plans “are required” to cover the items “specified” in such guidelines.⁷

100. Any non-exempt plan or issuer that fails to comply with the 2021 Guidelines, or previous guidelines, will face various and significant legal consequences.⁸

101. Issuers, plans, and employer plan sponsors thus must alter their coverage to include services specified for coverage in the Guidelines or face significant legal and financial liability.

102. Those parties do not face that same liability if they remove coverage of “instruction in fertility awareness-based methods” of family planning under the 2021 Guidelines.

V. The government did not meet the Administrative Procedure Act’s requirements in issuing the 2021 Guidelines.

A. Inadequate Notice

103. The 2021 Guidelines were not preceded by a notice of proposed rulemaking.

104. The 2021 Guidelines do not purport to be an interim final rule.

⁶ HRSA, *Preventive Guidelines and Screenings for Women, Children, and Youth*, <https://bit.ly/3NwssFU>.

⁷ See 2016 Guidelines (<https://bit.ly/3amHmAj>); 2019 Guidelines (<https://bit.ly/3MXmsG8>) and 2021 Guidelines (Exhibit A; see also <https://bit.ly/3wLtebi>).

⁸ See, e.g., *Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682, 696–98 (2014) (describing penalties for employers who fail to offer coverage outlined in the guidelines).

105. The government did not purport to rely on “good cause” to fail to pursue notice-and-comment rulemaking in issuing the 2021 Guidelines.

106. In October 2021, HRSA had announced draft changes to recommendations that influence the Guidelines (hereinafter “the October 2021 notice”).⁹

107. The October 2021 notice does not purport to be a proposed rule.

108. The October 2021 notice does not inform the public that HRSA planned to delete language that had required coverage of fertility awareness-based methods of family planning.

109. Instead, in describing draft changes to recommendations that influence the guidelines, the October 2021 notice described only three draft changes: “to clarify the terminology from contraceptive methods to contraceptives,” to “remove[] the term ‘female-controlled contraceptives’ to allow women to purchase male condoms for pregnancy prevention,” and to “further define[] the existing components of contraceptive follow-up care to include the management and evaluation of and changes to—including the removal, continuation, and discontinuation of—the contraceptive.” 86 Fed. Reg. at 59,742.

110. The October 2021 notice did not provide any rationale for deleting language requiring coverage of instruction in fertility awareness-based methods of family planning.

111. The October 2021 notice left the public to guess whether it proposed cutting coverage of instruction in fertility awareness-based methods from the guidelines altogether, or merely that the language concerning those methods was not mentioned or discussed in the notice because there was no plan to change that part of the contraceptive mandate.

⁹ HRSA, *Updated HRSA-Supported Women’s Preventive Services Guidelines: Contraception and Screening for HIV Infection*, 86 Fed. Reg. 59,741 (Oct. 28, 2021).

112. The October 2021 notice therefore did not adequately notify the public of a proposed change to fertility awareness-based methods of family planning coverage, or any reason for making that change, so as to adequately give the public an opportunity to comment on that change.

B. Irregular Public Comment Process

113. The October 2021 notice did not allow the public to submit comments about these changes to the responsible government agency, and the submission process did not use a public docket on the government website Regulations.gov.

114. Instead the October 2021 notice only allowed the public to submit comments to HRSA's private contractor, the Women's Preventive Services Initiative (WPSI).

115. The October 2021 notice was styled as an opportunity to comment to WPSI on what WPSI would *recommend*, concerning issues not inclusive of fertility awareness methods coverage. It was not an opportunity to comment to HRSA at all, and it was not an opportunity to comment on fertility awareness methods coverage specifically. HRSA stated that WPSI would "review the comments" on its recommendations," then, "[a]fter review, if approved, the HRSA Administrator accepts the proposed guidelines."¹⁰ The notice did not mention or discuss fertility awareness methods.

116. Nevertheless, some organizations, fearful that the current administration was hostile to fertility awareness-based methods of family planning, submitted comments to WPSI in response to the October 2021 notice, expressing concern and objection to any removal of coverage for those services.¹¹

¹⁰ HRSA, *Preventive Guidelines and Screenings for Women, Children, and Youth*, *supra*.

¹¹ See, e.g., Catholic Medical Association, *Public Comments Submitted to WPSI Nov-21 Re: Possible Changes to Fertility-Awareness Based Methods* (Nov. 21, 2021),

117. The government did not respond to those comments in issuing the 2021 Guidelines.

118. In issuing the 2021 Guidelines, the government did not respond to any comments submitted to WPSI from the October 2021 notice.

119. Upon information and belief, the government did not even read comments concerning fertility awareness methods coverage before issuing the final 2021 Guidelines.

120. Upon information and belief, those comments concerning fertility awareness methods coverage were never even in HRSA's or HHS's possession before issuing the 2021 Guidelines.

121. Comments submitted to WPSI in response to the October 2021 notice are not available for the public to access.

122. None of WPSI's own statements, recommendations, or implementation considerations constitute "part of the formal action by the Administrator under Section 2713," that is, the issuance of the 2021 Guidelines. *See* Exhibit A note *.

123. The government never solicited comments to HRSA or HHS itself about any change to the Guidelines.

124. The lack of response to any comments submitted to WPSI suggests that the government did not meaningfully consider those comments in issuing the Guidelines.

125. The agency cannot delegate its duty to collect public comments, review them, and respond to significant public comments, to an outside agency.

<https://bit.ly/3PIMLSg> & <https://bit.ly/3MLMpbT> (last visited May 24, 2022) (comments on behalf of U.S. Conference of Catholic Bishops, the National Catholic Bioethics Center and The Catholic Medical Association); Natural Womanhood, *Comments on Insurance Coverage for FAMs* (Nov. 21, 2021), <https://bit.ly/3NQVIaL> (last visited May 24, 2022) (comments of a non-profit women's health organization); FACTS, *Comment for the Women's Preventive Health Initiative Contraception Proposal*, <https://bit.ly/38H28u5> (last visited May 24, 2022).

126. The government cannot issue a binding final agency action without responding to significant public comments on the legal theory that its non-governmental contractor considered those comments so no response by the government was necessary.

127. Yet the 2021 Guidelines did not even purport to rely on such a legal theory.

128. WPSI, too, disclaims any practice of responding to public comments or obligation to do so: “At the present time, WPSI cannot provide responses to individual comments.”¹²

129. The government made no changes to the 2021 Guidelines in response to public comments.

130. The government did not meaningfully consider public comments, or consider them at all, in issuing the 2021 Guidelines.

C. No Reasoned Decision Making

131. In issuing the 2021 Guidelines, the government did not explain the substantive decision-making surrounding the change to fertility awareness methods coverage.

132. Instead, the agency simply published the group’s draft recommendations as its own supported guidelines, the 2021 Guidelines, on the HRSA website, without explanation or rationale with respect to fertility awareness methods coverage.¹³

133. In issuing the 2021 Guidelines, the government (1) gave no reason for its deletion of language covering fertility awareness-based methods of family planning; (2) discussed no reliance interests of health professionals and patients in such coverage being included in the Guidelines; and (3) discussed no alternatives to deleting this language.

¹² Women’s Preventive Services Initiative, *Public Comment*, <https://www.womenspreventivehealth.org/public-comment/> (last visited May 24, 2022).

¹³ Ex. A, 2021 Women’s Preventive Services Guidelines at 7–8.

134. The agency did not show in any other way its awareness of the change in the guidelines language concerning fertility awareness-based methods of family planning.

135. The agency cannot delegate its duty to make its own reasoned decision, and so any action by an outside group cannot substitute for the agency's own decision and judgment to be issued under the agency's own name and authority.

136. In any event, the agency did not purport to do so.

137. The agency did not state good cause for omitting any such procedure.

VI. Judicial relief is necessary and appropriate to halt the government's removal of fertility awareness-based methods from its contraceptive mandate.

138. Judicial relief is thus necessary and appropriate to hold unlawful and set aside the 2021 Guidelines' removal of language requiring coverage of fertility awareness-based methods of family planning.

139. Injunctive relief (temporary, preliminary, and permanent) is necessary to maintain the status quo in time for health plans and issuers to write and obtain government regulatory approval for their coverage to include this coverage, rather than to omit it based on this illegal change.

140. Injunctive relief is necessary to avoid patients' loss in health insurance benefits and surprise billing based on this illegal change.

141. Injunctive relief is necessary to avoid Dr. Tice-Harouff and other health professionals in the burgeoning field of fertility awareness-based methods instruction, from losing current and future patients and from losing financial compensation based on this illegal change.

142. Upon information and belief, health insurance issuers and government insurance regulators are already undergoing the planning and approval processes for plan or policy years that will begin after December 30, 2022.

143. Upon information and belief, it would cause significant confusion and hardship to health insurance issuers and plans to delay providing the injunctive relief requested here.

144. The relief requested must encompass the 2021 Guidelines' removal of coverage of fertility awareness-based methods of family planning, because Dr. Tice-Harouff's current and future patients span many states and individual health coverage situations, and plans will omit the required coverage and cause injury from the 2021 Guidelines if relief against the deletion itself is not afforded.

145. The government would suffer no harm from the relief requested, because with respect to fertility awareness-based methods instruction, the Guidelines would simply revert to language that has included for several years, and the 2021 Guidelines would not otherwise be affected.

146. Because health insurers around the country have already started their process of seeking approval for plan years beginning in January 2023, *see supra* note 4, Dr. Tice-Harouff and her patients will suffer irreparable harm unless this court issues a temporary restraining order delaying for one year the effective date of the 2021 Guidelines' change to language concerning fertility awareness-based methods instruction for one year, under 5 U.S.C. § 705 which explicitly authorizes that relief, so that plans, issuers, and state regulators can promptly become aware that this coverage cannot be dropped in these policies.

147. Dr. Tice-Harouff and her patients have no adequate remedy available at law.

CLAIMS FOR RELIEF

CLAIM ONE

ADMINISTRATIVE PROCEDURE ACT (5 U.S.C. § 706)

WITHOUT PROCEDURE REQUIRED BY LAW & CONTRARY TO LAW

148. Plaintiff re-alleges and incorporates herein, as though fully set forth, paragraphs 1–147 of this complaint.

149. Under the Administrative Procedure Act, agencies must follow public notice-and-comment procedures before they make final, binding actions.

150. Under the APA, a reviewing court must “hold unlawful and set aside agency action” if the agency action is “without observance of procedure required by law,” and “not in accordance with law.” 5 U.S.C. § 706(2)(A) & (D).

151. Under the APA, the court may issue temporary and preliminary injunctive relief and any other “necessary and appropriate process . . . to preserve status or rights pending conclusion of the review proceedings.” 5 U.S.C. § 705.

152. **Notice requirement.** The removal of instruction in fertility awareness-based methods of family planning from the 2021 Guidelines was not clearly set forth or adequately described, as to their nature or as to the agency’s reasons, in the October 2021 notice.

153. The public had no clear way to know that the government planned to eliminate this coverage language rather than simply make the listed changes alongside the longstanding language.

154. The public had no adequate notice of why the government would remove this language or what doing so might mean, and thus no adequate opportunity to comment on such a proposal and the government’s rationale for it, much less to comment on the impacts of such a change.

155. Thus the government violated the requirement that an agency must publish a general notice of proposed rulemaking in the Federal Register, including “a

statement of the time, place, and nature of public rule making proceedings” and “either the terms or substance of the proposed rule or a description of the subjects and issues involved,” or else find good cause to omit these procedures on the record. 5 U.S.C. § 553(b).

156. ***Comment requirement.*** The removal of instruction in fertility awareness-based methods of family planning from the 2021 Guidelines was not the subject of an opportunity for public comment to the government, either to HRSA or HHS.

157. The government did not collect, review, or consider public comments before issuing the 2021 Guidelines.

158. The comments solicited for submission to WPSI were not clearly for commenting to the government itself on its changes, rather than to WPSI for what changes it might recommend.

159. There was no specific request for comment on deleting language concerning fertility awareness methods coverage language, even while there were requests specifying other changes made in the notice.

160. The government did not treat the comments as public comments to it, nor did it receive, review, meaningfully consider, or consider at all those comments before issuing the 2021 Guidelines.

161. Thus the government violated the requirement for a legislative or substantive rule that “the agency shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments” 5 U.S.C. § 553(c).

162. The government made no finding of good cause for omitting either the notice or the comment procedures, nor did it purport to make such a finding.

163. Therefore the 2021 Guidelines’ removal of language requiring coverage of fertility awareness-based methods of family planning must be held unlawful, set aside, and preliminarily and permanently enjoined under the APA.

CLAIM TWO

ADMINISTRATIVE PROCEDURE ACT (5 U.S.C. § 706)

ARBITRARY, CAPRICIOUS, & AN ABUSE OF DISCRETION

164. Plaintiff re-alleges and incorporates herein, as though fully set forth, paragraphs 1–147 of this complaint.

165. Under the APA, a reviewing court must “hold unlawful and set aside agency action” if the agency action is “arbitrary, capricious, [or] an abuse of discretion” 5 U.S.C. § 706(2)(A).

166. The 2021 Guidelines, as to the removal of language requiring coverage of instruction in fertility awareness-based methods of family planning, are arbitrary, capricious, and an abuse of discretion.

167. The government failed to offer any rationale in its October 2021 notice describing why it was removing this coverage language, or even acknowledging that it planned to do so.

168. Likewise in the final 2021 Guidelines the government failed to offer any rationale for this change, or even an acknowledgement that it had made the change.

169. The government failed to describe any rational connection between the change made and some set of facts or problems.

170. The government failed to address, much less consider or adequately consider important aspects of the problem that led to or would be caused by removal of this language, such as the disruption caused by removing benefits or the degree of regulatory uncertainty that the new guidelines create.

171. The government completely failed to respond to multiple significant comments, submitted in the only comment process provided via HRSA’s contractor, which raised concerns and objections about deletion of this language.

172. In making this change, the government relied on facts, studies, and recommendations only from one side of the issue, and it ignored other evidence and experts.

173. The government failed to consider or adequately consider reliance interests of patients and health care professionals in maintaining the coverage language at issue.

174. In particular, the government failed to adequately consider the impact on health professionals and patients with medical, ethical, conscientious, and religious objections to other forms of family planning.

175. The government failed to consider or adequately consider alternatives to the deletion of this language, such as not deleting it.

176. The government's inadequate thought process reveals that it made an error of judgment.

177. The government itself has a non-delegable duty must publish adequate notices, accept comments, respond to comments, and engage in reasoned decision making.

178. Therefore the 2021 Guidelines' removal of language requiring coverage of fertility awareness-based methods of family planning must be held unlawful, set aside, and preliminarily and permanently enjoined under the APA.

PRAYER FOR RELIEF

For these reasons, Plaintiff Dr. Cami Jo Tice-Harouff, DNP, APRN, FNP-C, on behalf of herself and her patients, respectfully requests that this Court enter judgment against Defendants, and provide the following relief:

- A. That this Court declare unlawful, set aside, and vacate the 2021 Women's Preventive Service Guidelines as to the removal of the language requiring coverage of "instruction in fertility awareness-based methods" of family planning;

- B. That this Court render a declaratory judgment stating that the current Women's Preventive Service Guidelines *status quo ante* the 2021 Guidelines will remain in effect as to language requiring coverage of "instruction in fertility awareness-based methods" of family planning, including for plan and policy years beginning after December 30, 2022;
- C. That this Court render a declaratory judgment stating that HRSA's adoption or support of the 2021 Women's Preventive Service Guidelines, as to the removal of language requiring coverage of instruction in fertility awareness-based methods of family planning, is without observance of procedure required by law, and arbitrary, capricious, an abuse of discretion, and not in accordance with law under the Administrative Procedure Act;
- D. That this Court issue a temporary restraining order and preliminary injunction order under 5 U.S.C. § 705 to delay the effective date of the 2021 Guidelines' elimination of the language requiring coverage of instruction in fertility awareness-based methods of family planning until at least one year after the conclusion of this Court's review of this case;
- E. That this Court issue a temporary restraining order and preliminary and permanent injunction against Defendants, their officials, agents, employees, and all persons in active concert or participation with them, including their successors in office, using or applying the 2021 Guidelines to delete language requiring coverage of instruction in fertility awareness-based methods of family planning from the Women's Preventive Services Guidelines issued under 42 U.S.C. § 300gg-13, thereby maintaining that current language as set forth in previous Guidelines;
- F. That this Court vacate and remand the 2021 Guidelines to the government for further consideration, as to their deletion of language requiring coverage of instruction in fertility awareness-based methods of family planning.

- G. That this Court grant to Plaintiff reasonable costs and expenses of this action, including attorneys' fees, under any applicable law, including 28 U.S.C. § 2412;
- H. That this Court adjudge, decree, and declare the rights and other legal relations of the parties to the subject matter here in controversy so that such declarations will have the force and effect of final judgment;
- I. That this Court retain jurisdiction of this matter to enforce this Court's order; and
- J. That this Court grant such other relief as this Court deems just and proper.

Respectfully submitted this 25th day of May, 2022.

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DECLARATION UNDER PENALTY OF PERJURY

I, Cami Jo Tice-Harouff, a citizen of the United States and a resident of Texas, and as Plaintiff, declare under penalty of perjury under 28 U.S.C. § 1746 that the above is true and correct to the best of my knowledge.

Executed this 23rd day of May, 2022, at Longview, Texas

/s/ Cami Jo Tice-Harouff_____

Cami Jo Tice-Harouff

[Signature filed electronically with original maintained by counsel]